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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/655,704	09/06/2000	Walter M. Bain	1311.APT.PT	9130

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MORRIS, BATEMAN, O'BRYANT & COMPAGNI
136 SOUTH MAIN STREET
SUITE 700
SALT LAKE CITY, UT 84101

EXAMINER

CHANCE, JANET D

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 03/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/655,704

Applicant(s)

BAIN, WALTER M.

Examiner

Janet D. Chance

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 September 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Recent Statutory Changes to 35 U.S.C. § 102(e)

On November 2, 2002, President Bush signed the 21st Century Department of Justice Appropriations Authorization Act (H.R. 2215) (Pub. L. 107-273, 116 Stat. 1758 (2002)), which further amended 35 U.S.C. § 102(e), as revised by the American Inventors Protection Act of 1999 (AIPA) (Pub. L. 106-113, 113 Stat. 1501 (1999)). The revised provisions in 35 U.S.C. § 102(e) are completely retroactive and effective immediately for all applications being examined or patents being reexamined. Until all of the Office's automated systems are updated to reflect the revised statute, citation to the revised statute in Office actions is provided by this attachment. This attachment also substitutes for any citation of the text of 35 U.S.C. § 102(e), if made, in the attached Office action.

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 in view of the AIPA and H.R. 2215 that forms the basis for the rejections under this section made in the attached Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35 U.S.C. § 102(e), as revised by the AIPA and H.R. 2215, applies to all qualifying references, except when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. For such patents, the prior art date is determined under 35 U.S.C. § 102(e) as it existed prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. § 102(e)).

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 102 prior to the amendment by the AIPA that forms the basis for the rejections under this section made in the attached Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

For more information on revised 35 U.S.C. § 102(e) visit the USPTO website at www.uspto.gov or call the Office of Patent Legal Administration at (703) 305-1622.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the application filed 6 September 2000. Claims 1-32 are pending. The IDS statement filed 4 March 2002 has been entered and considered.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "8" has been used to designate both the "patient interface portion" and the right side column of the patient interface portion of Figure 1. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "160" has been used to designate both the sensor and stocking access door of Figure 2. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: Element 190 has been described as secured line (page 33, line 3), and as actuator (page 35, line 6 and page 34, line 4). Element descriptions must be consistent throughout the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-7, and 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Liff et al. (5,713,485).

(A) As per claim 1, Liff teaches an automated prescription dispensing system comprising:

a) a patient interface (48 or 38) having a data interface configured for entering information correlated to the patient and a receptacle through which medication is dispensed (Liff; Figure 1, col. 4, lines 40-65);

b) a dispenser (20) disposed in communication with the patient interface portion for holding and dispensing medication (Liff; Figure 1, col. 4, lines 40-65); and

c) a controller (42) in communication with the dispensing portion for selectively controlling the dispensing of medication disposed in the dispensing portion (Liff; Figure 1, col. 4, lines 40-65).

Art Unit: 3626

(B) As per claims 2-6, and 15, Liff teaches the automated prescription dispensing system of claim 1, wherein the patient data interface comprises a keyboard (50), a magnetic card reader (38), a display screen (48), a printer (56, 54), a speaker, and a scanner (Liff; col. 7, lines 10-20, col. 10, lines 5-15, col. 4, lines 40-65, col. 2, lines 5-30, col. 5, lines 1-25).

(C) As per claim 7, Liff teaches, the automated prescription dispensing system of claim 1, wherein the dispenser comprises a plurality of medication receiving slots (76) (Liff; Figure 1).

(D) As per claim 11, Liff teaches the automated prescription dispensing system of claim 7, further comprising a plurality of sensors for determining the presence of medication within the plurality of receiving slots (Liff; col. 6, lines 5-12).

(E) As per claim 12, Liff teaches, the automated prescription dispensing system of claim 7, wherein the controller is configured to track the location of medication disposed in on of the plurality of receiving slots (Liff; col. 6, lines 5-35).

(F) As per claim 13, Liff teaches, the automated prescription dispensing system of claim 1, wherein the control comprises a data interface for entering information about each prescription loaded into the dispenser (Liff; col. 8, line 53 to col. 9, line 40).

Art Unit: 3626

(G) As per claim 14, Halvorson teaches the automated prescription dispensing system of claim 13, wherein the data interface comprises a keyboard (50) (Liff; Figure 1).

(H) As per claim 16, Liff teaches the automated prescription dispensing system of claim 1, wherein the controller comprises a processor programmed to record information regarding the location of medications within the dispenser (Liff; col. 6, lines 10-35).

(I) As per claim 17, Liff teaches the automated prescription dispensing system of claim 1, wherein the controller further comprises a communications interface (52) for communicating with remote locations (Liff; Figures 1, 4).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8-10, 18-23, and 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liff as applied to claims 1 and 18 above, and further in view of Halvorson (4,847,764)..

(A) As per claims 8-10, Liff teaches, the automated prescription dispensing system wherein at least one door comprises a dispensing door (68) for selectively releasing medication from the receiving slot (Liff; col. 7, line 40 to col. 8, line 5) and having outside doors of the dispenser that lock (Liff; col. 4, lines 40-55). However, Liff does not expressly teach a one door adjacent each slot for selectively passing control through the dispenser including a door selectively preventing placement of medication onto the receiving slot. Halvorson teaches an automated prescription dispensing system wherein the dispenser comprises two door disposed adjacent each receiving slot, a stocking access door for selectively controlling the passage of medication into the receiving slot, and a medication access door for selectively releasing medication from the receiving slot (Halvorson; col. 3, lines 46 to col. 4, line 6). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the stocking access door of Halvorson to the medication dispensing system of Liff with the motivation of reducing medication errors (Halvorson; col. 2, line 41).

(B) As per claim 18, Liff teaches a method for automated prescription dispensing comprising:

a) filling an inventory order by obtaining a container with medication therein (Liff; col. 9, lines 1-25). However it is unclear in Liff if the inventory order is made up of prescriptions. Halvorson teaches the ordering of prescriptions and gathering the required prescriptions that need to be filled to determine the restocking of the dispenser and then preparing of the prescriptions for the dispenser (Halvorson; col. 10, lines 1-50, col. 12, lines 45-60, col. 19, lines 1-60 and col. 21, line 30 to col. 22, lines 35). It would have been obvious to one of ordinary skill

Art Unit: 3626

in the art at the time of the invention to add the step of filling prescriptions of Halvorson to the filling of the inventory order of Liff with the motivation of improving inventory control since inventory would be filled to meet precise demand;

b) loading the prescription into a dispenser (Liff, col. 9, lines 25-30); and

c) dispensing the prescription to a patient in response to input of data correlated to the patient (Liff, col. 5, lines 14-25).

(C) As per claim 19, Liff teaches the method according to claim 18, wherein method comprises placing the prescription into a receiving slot of a dispenser having a plurality of receiving slots disposed therein (Liff, col. 5, lines 10-20 and lines 40-60).

(D) As per claim 20, Liff teaches loading a dispenser with medication tracked by barcode (Liff, col. 2, lines 10-20), entering patient information into a dispenser either via a computer interface or card reader and dispensing the appropriate medication (Liff, col. 5, lines 14-25 and col. 4, lines 54-61). Examiner respectfully submits that in order for these steps to happen the receiving slot in which the prescription is placed must be correlated with information regarding the patient. Therefore, the system of Liff performs this step.

(E) As per claim 21, Liff teaches the method according to claim 20, further comprising releasing the prescription from the dispenser in response to input of data correlated to the patient (Liff, col. 5, lines 14-25).

(F) As per claim 22, Liff teaches the method accord to claim 18, and wherein the method comprises dispensing the prescription after the user enters a password (i.e., personal identification number) (Liff, col. 8, lines 20-55).

(G) As per line 23, Liff teaches, a method for dispensing medication from a dispenser having a plurality of receiving slots, the method comprising:

a and d) restocking a dispenser with locks on the outside doors (Liff, col. 9, lines 19-34, col. 4, lines 40-55). However Liff does not expressly teach the opening or closing of an available receiving slot. Halvorson teaches the control of locking and unlocking doors including a stocking access door and a restocking plan requires someone to operate the controller to open the stocking access door to the receiving slot (Halvorson; col. 3, lines 55-65, col. 21, lines 30 to col. 22, line 35). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the stocking access door and the step of opening of an available receiving slot of Halvorson to the dispensing system and process of Liff with the motivation of increasing control of pharmaceuticals in the station;

b) inputting information regarding a prescription (Liff, col. 6, lines 12-19);

c) disposing the prescription in the receiving slot (Liff, col. 6, lines 12-19 and col. 9, lines 20-45);

e) dispensing the prescription from the receiving slot to a patient (Liff, col. 5, line 14-25).

Art Unit: 3626

(H) As per claim 28, Liff teaches a method for billing prescriptions, the method comprising:

a) determining inventory requirements (Liff; col. 9, lines 1-25). However it is unclear in Liff if the inventory requirements are the result of prescriptions or lack of inventory. Halvorson teaches filling a prescription Halvorson teaches the ordering of prescriptions and gathering the required prescriptions that need to be filled to determine the restocking of the dispenser and then filling of the prescriptions for the dispenser (Halvorson; col. 10, lines 1-50, col. 12, lines 45-60, col. 19, lines 1-60 and col. 21, line 30 to col. 22, lines 35). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the step of filling prescriptions of Halvorson to the filling of the inventory order of Liff with the motivation of improving inventory control since inventory would be filled to meet precise demand;

b) loading the prescription into an automated dispensing system (Liff; col. 9, line 19-30);

c) dispensing the prescription to a patient in response to information correlated to the patient (Liff; col. 5, lines 14-25); and

d) generating a bill responsive to dispensing of the prescription (Liff; col. 9, lines 13-18).

(I) As per claim 29, Liff teaches a method for more efficiently filling prescriptions, the method comprising:

a-b) Liff teaches the collecting information for a plurality of drugs to restock inventory at a central processing station (Liff; col. 9, lines 1-25). However, it is unclear in Liff if the drug information includes prescription information. Halvorson teaches the collecting of information for a plurality of prescriptions at a central processing location that need to be filled to determine

Art Unit: 3626

the restocking of the dispenser and then filling of the prescriptions for the dispenser (Halvorson; col. 10, lines 1-50, col. 12, lines 45-60, col. 19, lines 1-60 and col. 21, line 30 to col. 22, lines 35). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the step of filling prescriptions of Halvorson to the filling of the inventory order of Liff with the motivation of improving inventory control since inventory would be filled to meet precise demand; and

c) transporting the prescriptions to a plurality of local pharmacies (Liff; col. 9, lines 19-35).

(J) As per claim 30, Liff teaches the method according to claim 29, wherein the method comprises receiving prescription information at local pharmacies (46) and relaying the information to the central processing location (100) (Liff; Figure 4, col. 7, lines 24-40, col. 8, lines 22-35).

(K) As per claim 31, Liff teaches the method according to claim 29, wherein the method comprises organizing the order and filling the order by groups based on the medication ordered (Liff; col. 8, lines 53-67, col. 6, lines 13-35). However, it is unclear if the orders are prescriptions. Halvorson teaches the ordering of prescriptions and gathering the required prescriptions that need to be filled to determine the restocking of the dispenser and then filling of the prescriptions for the dispenser (Halvorson; col. 10, lines 1-50, col. 12, lines 45-60, col. 19, lines 1-60 and col. 21, line 30 to col. 22, lines 35). It would have been obvious to one of

Art Unit: 3626

ordinary skill in the art at the time of the invention to add the step of filling prescriptions of Halvorson to the filling of the inventory order by groups of Liff with the motivation of improving inventory control since inventory would be filled to meet precise demand.

(L) As per claim 32, Liff teaches the method according to claim 29, further comprising loading the prescriptions into an automated dispensing system at the local pharmacy (Liff, col. 9, lines 19-45, col. 1, lines 60-67, col. 6, lines 59-67).

9. Claims 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liff et al. (5,713,485), further in view of Halvorson (4,847,764) and further in view of Anonymous (Anonymous, "Developers Should Link Physicians and Pharmacies", *Electronic Claims Processing Report*).

(A) As per claims 24, Liff teaches a method for verifying a refill prescription, the method comprising:

a) obtaining information regarding a prescription to be refilled (Liff, col. 8, lines 22-55);

b) However, Liff fails to teach determining whether a new refill exceeds an authorized number of refills. Halvorson teaches the determination of maximum doses received and minimum hours between doses to analyze if the medicine will be dispensed or placed on hold (Halvorson; col. 13, lines 55-58 and col. 23, lines 2-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the determination of exceeding

Art Unit: 3626

authorized refills of Halvorson to the dispensing system of Liff with the motivation of reducing medication errors by providing the ability to suspend all or specific orders for a patient for a variety of conditions (Halvorson; col. 2, lines 40-62); and

c) The combined teachings of Liff and Halvorson teach the determination of whether the refill exceeds the authorized number of refills. However, the combined teachings of Liff and Halvorson fail to teach sending an electronic inquiry to a doctor requesting authorization to fill a refill prescription, which exceeds the authorized number of refills. The *Electronic Claims Report* teaches the sending an electronic inquiry to a doctor requesting authorization to fill a refill prescription, which exceeds the authorized number of refills (*Electronic Claims Report*; page 2, paragraph 8). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the electronic inquiry requesting refill authorization of the *Electronic Claims Report* to the dispensing networked system of the combined teachings of Liff and Halvorson with the motivation of “saving the doctor, the pharmacist and even the patient unneeded hassles” (*Electronic Claims Report*; page 2, paragraph 13).

(B) As per claims 25 and 27, Liff teaches the practitioner confirming data regarding a refill (Liff; col. 8, lines 48-52). However, Liff does not teach the step of receiving an electronic authorization or denial of confirmation from a doctor. Halvorson teaches the receipt of a change order in response to a prescription being placed on discontinued status due to doses being exceeded (Halvorson; col. 16, lines 50-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the receipt of a authorization confirmation of

Art Unit: 3626

Halvorson to the dispensing system of Liff with the motivation of providing “automatic daily evaluation of medication due to discontinue (Halvorson; col. 2, lines 51-52).

However the combined teachings of Liff and Halvorson do not teach the step of receiving a denial of confirmation from a doctor. The *Electronic Claims Report* teaches the receiving a denial of confirmation from a doctor (*Electronic Claims Report*; page 2, paragraph 8). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the step of receiving a denial of confirmation from a doctor of the *Electronic Claims Report* to the dispensing networked system of the combined teachings of Liff and Halvorson with the motivation of “saving the doctor, the pharmacist and even the patient unneeded hassles” (*Electronic Claims Report*; page 2, paragraph 13).

(C) As per claim 26, Liff teaches the practitioner confirming data regarding a refill (Liff; col. 8, lines 48-52). However, Liff does not teach the method according to claim 25, further comprising filling the prescription in response to the electronic authorization confirmation.

Halvorson teaches the receipt of a change order in response to a prescription being placed on discontinued status due to doses being exceeded allowing the prescription to be filled (Halvorson; col. 16, lines 50-65). It would have been obvious to one of ordinary skill in the art at the time of the invention to add the filling of a prescription after authorization confirmation of Halvorson to the dispensing system of Liff with the motivation of providing “automatic daily evaluation of medication due to discontinue (Halvorson; col. 2, lines 51-52).

Art Unit: 3626

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not relied upon art teaches a programmable medication dispensing system that uses speakers to annunciate audible alarms (5,408,443), a drug dispensing apparatus that uses a user ID and PIN number or biometric identification to dispense drugs to patients (5,377,864), an automatic medication dispensing system in which the physician must approve any deviation from programmed norms (US 6,352,200 B1), an article from *Drug Topics* in which oral authorizations are proven to be old and well known in the art and electronic authorizations by FAX are discussed (Fitzgerald, Walter, "Fax for facts. (facsimile prescriptions)"), and an article from *Business Wire* that discusses the product "PCS Link" and its capability to allow doctors to authorize or deny refill requests electronically (Anonymous, "PCS expands its leadership position in M.D. connectivity with new agreement; Potential for up to 100,000 additional physicians to be connected.").

11. Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 305-7687 [Official communications]
(703) 746-7238 [After Final communications, labeled "Box AF"]

Hand delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th floor receptionist.

Art Unit: 3626

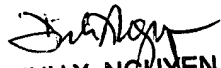
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet D. Chance whose telephone number is (703) 305-5356.

The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (703) 305-9588. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-7687 for regular communications and (703) 746-7238 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

jdc
March 7, 2003


DINH X. NGUYEN
PRIMARY EXAMINER